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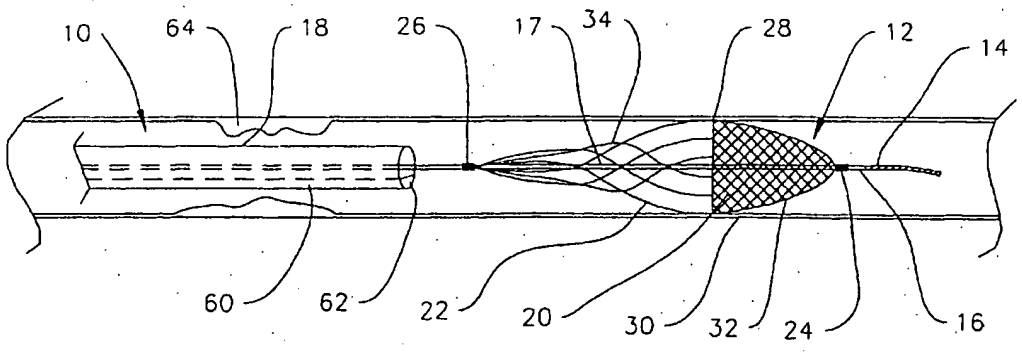
(54) Title: DISTAL PROTECTION DEVICE



(57) Abstract: The present invention is a distal protection device for use during a vascular treatment, such as angioplasty or atherectomy. A filter assembly located on the distal end of a delivery member is deployed distally of the vascular region to be treated to capture emboli released during and immediately after the procedure. The filter is then retracted to retain any captured emboli and then removed from the patient.

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therapies use laser or RF signals to superheat or vaporize the thrombis within the vessel. Emboli loosened during such procedures are removed from the patient through the catheter.

During each of these procedures, there is a risk that emboli dislodged by the procedure will migrate through the circulatory system and cause clots and strokes. Thus, practitioners have approached prevention of escaped emboli through use of occlusion devices, filters, lysing and aspiration techniques. In atherectomy procedures, it is common to remove the cut or abraded material by suction though an aspiration lumen in the catheter or by capturing emboli in a filter or occlusion device positioned distal of the treatment area.

Prior art filters or occlusion devices are associated with either a catheter or guidewire and are positioned distal of the area to be treated. One prior art collapsible filter device includes a filter deployed by a balloon distal of a dilatation balloon on the distal end of a catheter. The filter consists of a filter material secured to resilient ribs. The ribs are mounted at the distal end of the catheter. A filter balloon is located between the catheter exterior and the ribs. Inflation of the filter balloon extends the ribs outward across the vessel to form a trap for fragments loosened by a dilatation balloon. When the filter balloon is deflated, the resilient ribs retract against the catheter to retain the fragments during withdrawal of the catheter.

Another prior art filter arrangement includes several filter elements fastened in spaced apart arrangement along the length of a flexible elongate member. This forms an open-mouthed tubular sock like arrangement to capture the emboli within. The filter is collapsed around the flexible elongate member by wrapping it spirally.

One problem associated with known filter arrangements is that emboli may not be fully contained within the filter. Emboli can build up in the area just proximal of the filter, including any frame portion of the filter assembly. As the filter is closed, emboli not fully contained in the filter can escape around the filter into the circulatory system and cause potentially life threatening strokes. While the blood flow is inhibited when an occlusion device is used during the procedure, emboli can escape as the occlusion device is withdrawn from the treatment area.

Therefore, what is needed is a filter arrangement that addresses the problem of emboli not fully contained in the filter assembly or captured by an occlusion device. Furthermore, there is a need for a filter assembly that is adaptable for delivery with standard PTA balloon or stent delivery catheters. Additionally there is a need for a filter arrangement that is secure by being mounted at its distal and proximal ends to the delivery member ensuring proper placement of the filter throughout deployment, capture of the emboli and subsequent removal of the filter and captured emboli.

SUMMARY OF THE INVENTION

The present invention is a distal protection device for use in vascular procedures. The distal protection device includes a filter assembly adjacent the distal end of a delivery member used in the procedure. The proximal and distal ends of the filter assembly are fixed to the delivery member such that the ends cannot move longitudinally along the delivery member, but may rotate independently of the delivery member core. The filter assembly includes an expandible frame with

distal end of the filter slides distally on the delivery member, extending the length of the filter. The filter of this embodiment may also include a frame that is densely braided from end-to-end to form a basket with fine pores. The filter also has large inlet openings that are formed in the proximal end after braiding. The deployed shape of this filter embodiment is generally that of a teardrop, the proximal end having a generally obtuse cone and the distal end having a generally acute cone. A cylindrical well defines the filter body between the proximal and distal cones.

The sheath is configured to be used with either a rapid exchange arrangement or an over-the-wire arrangement as well known to those skilled in the art.

BRIEF DESCRIPTION OF DRAWINGS

For a more complete understanding of the features, aspects, and advantages of the present invention, reference is now made to the following description, appended claims, and accompanying drawings wherein:

Figure 1 is a side view of a catheter and delivery member incorporating a distal protection device of the present invention, with the distal protection device shown deployed in a vessel;

Figure 2 is a side view taken of the distal portion of a catheter and delivery member incorporating a distal protection device of the present invention, with the distal protection device shown constrained in the catheter, which is shown in section;

practitioner desires to capture material that may be dislodged during the procedure. The distal protection device 10 includes a filter assembly 12 located adjacent the distal end 14 of a delivery member 16. In this preferred embodiment delivery member 16 can be a modified guidewire assembly, hereinafter referred to as either "delivery member," "guidewire," or "core wire." Filter assembly 12 is delivered, deployed and retrieved by a sheath 18 arranged to be slid over filter assembly 12. When the distal protection device 10 is in a constrained position, filter assembly 12 is collapsed within sheath 18 as shown in Figure 2. When filter assembly 12 is deployed, sheath 18 is withdrawn releasing filter assembly 12 as shown in Figure 1.

Filter assembly 12 includes a filter 20 and a frame 22 and is secured to delivery member 16 at its distal portion 24 and proximal portion 26. Preferably, the filter assembly ends 24 and 26 are fixed in the longitudinal position, but are capable of rotational movement independent of the guidewire core 17 while maintaining the longitudinal position. Filter 20 is formed from a suitable mesh or porous material that will filter emboli from blood while permitting sufficient perfusion therethrough. For example, a porous filter can be formed from urethane material by adding salt, sugar or other granular particles during the casting of the urethane filter. Following the cutting and curing processes, these granular particles are dissolved forming a porous urethane filter as well known to those skilled in the art. Other suitable filter materials may include nylon, ePTFE, teflon, kevlar and the like having an appropriate porous construction to filter emboli from blood passing through the filter.

A variety of strut configurations are suitable including the braid configuration shown in Figure 1. Struts 56 of filter assembly basket 58 shown in Figure 4 have a dense braid on distal portion 61 that transitions to a less dense braid on proximal portion 63. Filter material may be located on distal portion 61 either by having a separate filter material or by dip coating selected portions of the basket 58 as discussed above with respect to the embodiment shown in Figure 3. Alternatively, the braid of the struts 56 may be sufficiently dense on distal portion 61 to act as a porous filter thus obviating the need for a separate filter material or selective dip coating of basket 58. Filter assembly basket 58 is fixed to the guidewire 65 at its proximal end 66 and distal end 68. Again, filter assembly basket 58 is preferably fixed at a longitudinal position on guidewire 65 where it is capable of rotational movement independent of the guidewire core. A sheath 70 is used to deploy filter assembly basket 58.

Filter assembly 80 shown in Figure 5 is similar to the filter arrangement of Figure 1. Frame 82 consists of a distal ring 84 formed from a sinusoidal element. Extending from ring 84 to the guide wire 86 are helical members 90. For example, one such member 90 extends between apex 88 of ring 84 and guidewire 86. Distal end 96 of filter 92 is secured to guidewire 86.

Sheath 98 includes an aspiration lumen 100 and lysing lumen 102. While two lumens are shown, as known to those skilled in the art, only an aspiration or lysing lumen may be incorporated in sheath 98. Sheath 98 also includes a short guidewire lumen 104 resulting in a sheath configured as a rapid exchange sheath. A preferred construction for either of sheaths 18 or 98, as shown in Figure 4, is to incorporate a more radiopaque distal region 67 into the shaft. Distal region 67 is

such as a coronary artery, while still having enough room to place the filter downstream of the treatment site. The proximal surface 130 is a flat plane that is perpendicular to cylindrical central well 132. The flat shape of proximal surface 130 adds negligible axial length to the filter 120, especially in comparison to proximal portion 66 of filter assembly basket 58 in Figure 4. Considering proximal surface 130 as a cone, as shown in other embodiments, it has an included angle of 180°.

In filter assembly 112, filter 120 is mounted adjacent the distal end 114 of a delivery member, or guidewire 116, which preferably has a slender shaft 117 with a surrounding coil spring 119 at distal end 114. Preferably, coil spring 119 ends proximally within filter 120. Proximal end 166 and distal end 168 of filter 120 are attached to guidewire 116. Proximal end 166 is preferably fixed to guidewire 116 using solder, braze or adhesives. Alternatively, as shown in Figure 10, proximal end 266 can be attached to guidewire 116 such that a limited amount of rotation is permitted between guidewire 116 and filter 120. Helical member 140 loosely surrounds guidewire 116 with its proximal and distal ends secured thereto, and extends proximal and distal to filter proximal end 266. Proximal end 266 is secured between the proximal and distal ends of member 140, without this bond attaching to underlying guidewire 116, such that the full length of member 140, except for its ends, is capable of limited rotation with respect to guidewire 116.

Distal end 168 is preferably mounted to tubular slider 170, which provides a sliding mount over distal end 114 of guidewire 116. Slider 170 may be formed from any suitable plastic or metallic material, preferably a thin-walled polyimide thermoset polymer. Adhesive is preferably

In another embodiment, stop 172" is formed by a coil spring, as shown in Figure 12. Stop 172" has a proximal end secured to core wire 116 and a distal end secured to distal end 266. In the deployed configuration, the coils of stop 172" are stacked together, preventing further shortening of filter 220. During compression of filter 220, ends 266 and 268 separate and stop 172" elongates, increasing tension force therein as the coils are separated. This tension force may be useful to deploy stent 220 upon release from sheath 18 or sheath 98. Having an internal deployment force from stop 172" makes it easier to fabricate filter 220 from materials other than shape memory alloys such as NiTi (nitinol), because filter 220 does not need to provide its own deployment force.

Filter assembly 112 is similar to filter assembly basket 58 shown in Figure 4, wherein the struts 56 alone make the filter basket by using a densely braided structure. Filter 120 is formed with a generally constant pitch braid, preferably providing a uniform pore size of approximately 75-125 microns, such that no additional filter material is necessary.

Proximal surface 130 includes inlet ports 190, as shown in Figure 7. Ports 190 are formed after filter 120 has been braided by inserting metal shaping mandrels into the proximal surface and applying a heat treatment to the braid of filter 120. Ports 190 are best described when viewed from the proximal end of the filter assembly 112 because this view shows the shapes of the mandrels used to make inlet ports 190, even when the proximal surface of the filter is other than flat, as in the sixth embodiment of the invention, which will be discussed below. Ports 190 provide filter inlet openings that are substantially larger than the size of the pores in filter 120. Ports 190 may have a variety of preferably rounded, symmetrical shapes, each having an axis 192 in-plane with

The deployment of filter assembly 12 will now be described, although the procedure explained is equally applicable to any of the filter assembly embodiments disclosed herein. The deployment mechanism includes sheath 18 that is sized to travel over delivery member 16 and receive the filter assembly 12 therein as shown in Figure 2. Sheath 18 may incorporate an aspiration lumen 60. Additionally, sheath 18 may incorporate a flushing lumen 62 (Figure 1) to enable the practitioner to flush the filter assembly with a lysing agent prior to and during the procedure to remove emboli lodged on the struts. The sheath is constructed for use as either an over-the-wire system shown with sheath 18 in Figure 1, or a rapid exchange system, shown with sheath 98 in Figure 5.

In operation, sheath 18 is extended over delivery member 16 until it fully covers filter assembly 12 as shown in Figure 2. Sheath 18, filter assembly 12 and delivery member 16 are then inserted into the patient and routed to the area to be treated, designated as 64 in Figure 1. Filter assembly 12 and sheath 18 are positioned past the area 64 to be treated. Sheath 18 is then withdrawn, releasing struts 34 of filter assembly 12. As struts 34 resume their unrestrained position, filter 20 expands to fill the cross sectional area of the vessel. Sheath 18 may then be completely withdrawn from delivery member 16 and then an appropriate second device, such as a treatment catheter, can be routed over delivery member 16 to the treatment area.

During and after the treatment such as, an angioplasty, atherectomy or the like procedure, emboli can be dislodged. The emboli will travel downstream and be captured by filter 20. The treatment catheter is removed after the procedure and sheath 18 is loaded on delivery member 16

We claim:

1. A distal protection device comprising:

a delivery member having a proximal end and a distal end;

a filter assembly being transformable between a deployed configuration and a collapsed configuration, the deployed configuration having a cylindrical well, a distal cone, a proximal cone, and a transition from the well to the proximal cone, said filter assembly having a structure with pores and being adapted to include a plurality of inlet openings in the proximal cone, the inlet openings being substantially larger than the pores, said assembly being mounted adjacent the distal end of said delivery member.

2. The distal protection device of claim 1 further comprising a sheath that is selectively moveable over said delivery member for transforming said filter assembly between the deployed configuration and the collapsed configuration.

3. The distal protection device of claim 1 further comprising the proximal cone having an included angle that is generally obtuse.

4. The distal protection device of claim 3 wherein the included angle of the proximal cone is 180°.

11. The distal protection device of claim 8 wherein each of said at least one inlet opening is sized to maximize the length of the axis of each said opening.

12. The distal protection device of claim 11 wherein the proximal cone includes the maximum number of said inlet openings that will fit therein.

13. A vascular filter apparatus comprising:

a core wire having proximal and distal ends,

a filter arranged around said core wire, said filter having a proximal end, a distal end, a deployed configuration and a collapsed configuration, the deployed configuration having a cylindrical central well, a distal cone, a proximal cone, and a transition from the central well to the proximal cone, the proximal cone having an included angle that is generally obtuse, said filter having a structure with pores and being adapted to include a plurality of inlet openings in the proximal cone, the inlet openings being substantially larger than the pores, the distal end of said filter being coupled to the core wire adjacent its distal end and the proximal end of the filter being coupled to the core wire.

14. The vascular filter apparatus of Claim 13, further comprising a sheath slidably mounted on said core wire and having proximal and distal ends, the distal end of said sheath having a

20. A vascular filter apparatus comprising:

a core wire having proximal and distal ends,

a filter arranged around said core wire, said filter having a proximal end, a distal end, a deployed configuration and a collapsed configuration, the deployed configuration having a distal cone, a proximal cone, a variable length and a deployed length, the proximal end of the filter being attached to the core wire, and

a tubular member coupled to the core wire for preventing the variable length from becoming shorter than approximately the deployed length.

21. A vascular filter of claim 20 wherein said tubular member is slidingly mounted over said core wire adjacent its distal end, the distal end of said filter being secured to said tubular member.

22. The vascular filter apparatus of claim 21, wherein said tubular member extends into the filter a sufficient length to prevent the variable length from becoming shorter than approximately the deployed length.

23. The vascular filter apparatus of claim 20 wherein at least one end of the tubular member is fixedly coupled to said core wire between the proximal and distal ends of said filter.

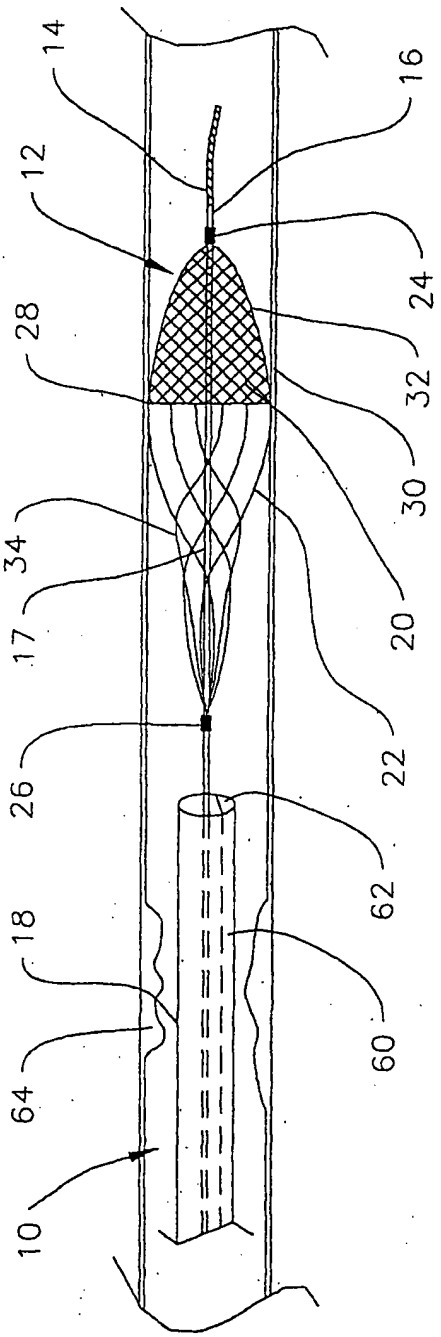
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FIG. 1

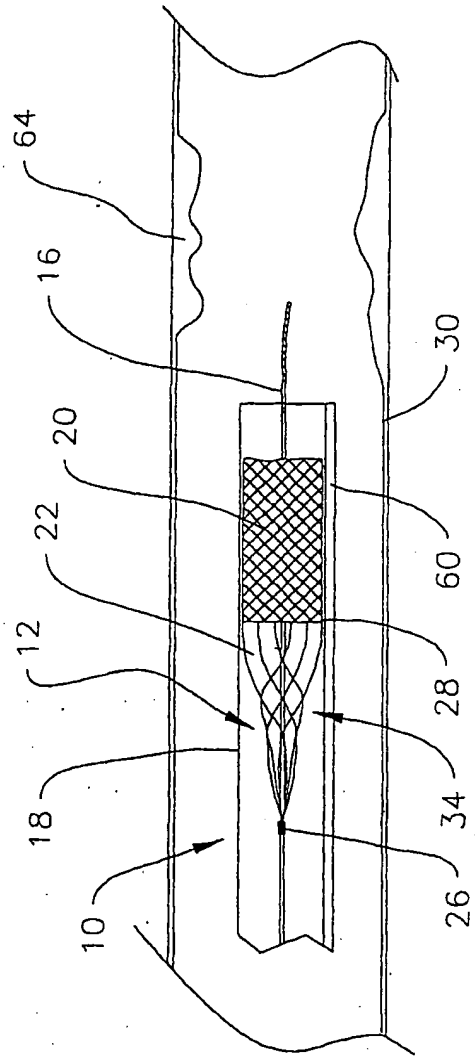
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FIG. 2

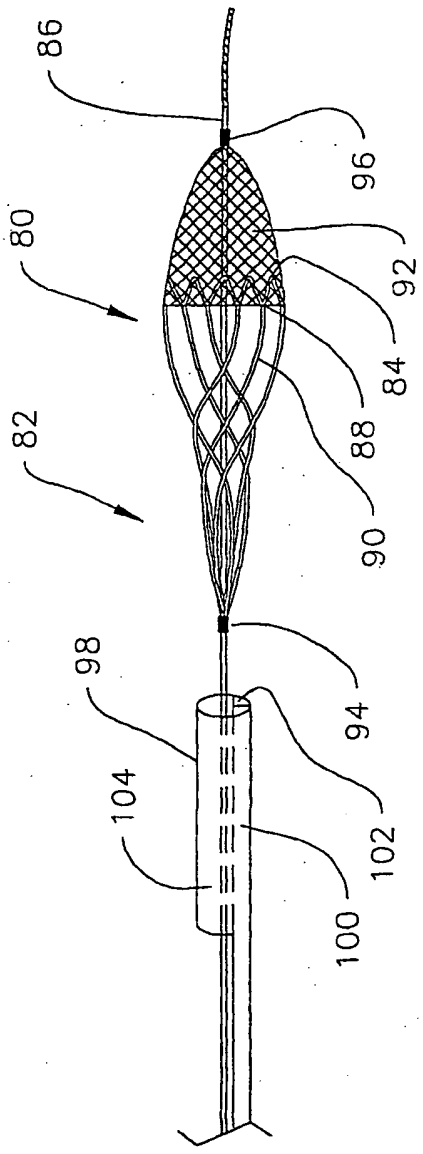


FIG. 5

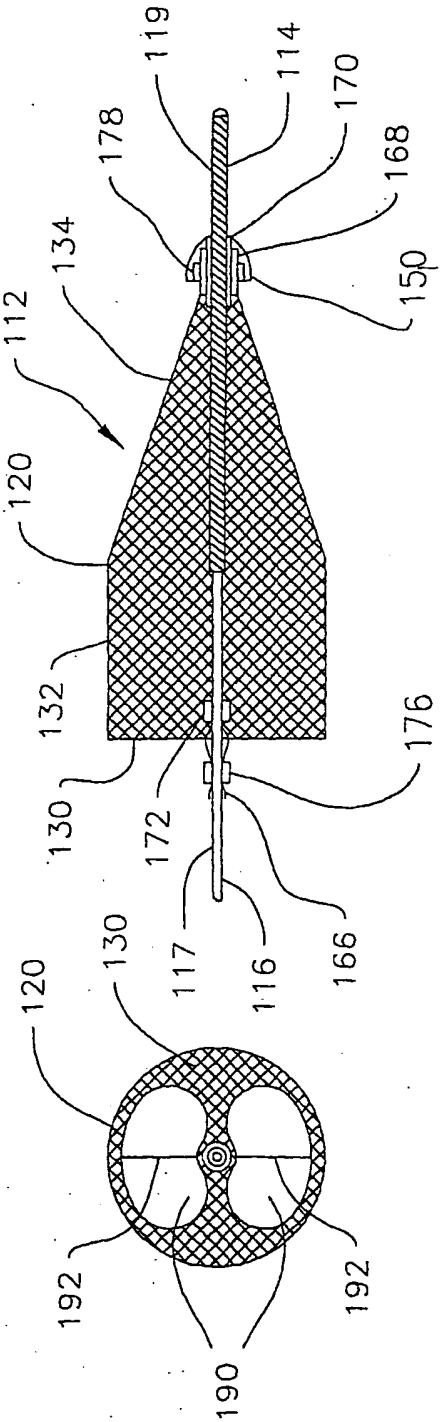


FIG. 6

FIG. 7

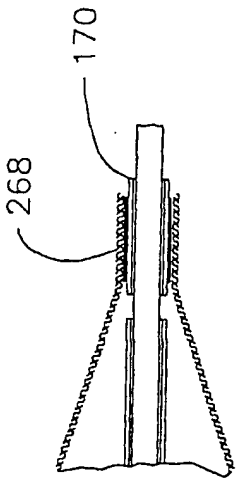
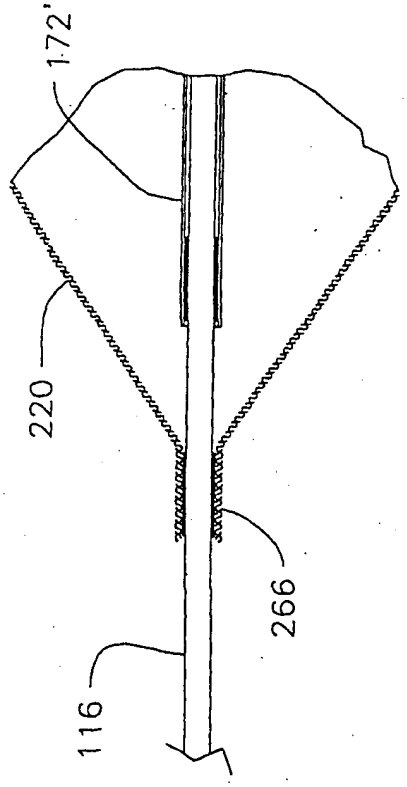


FIG. 11



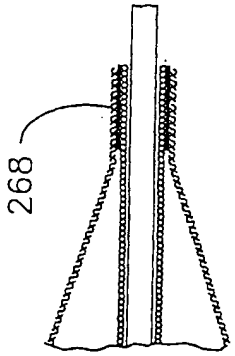


FIG. 12